

## Definitions

**COMPLIANCE ACHIEVEMENT:** The observed repair, modification, or adjustment of a violative condition, or the repair, modification, adjustment, relabeling, or destruction of a violative product when either the product or condition does not comply with the Acts enforced by the agency.

**CIVIL MONEY PENALTY:** A monetary penalty for a non-criminal action that is assessed by FDA or the courts for violations of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

**INDICTMENT:** A formal accusation by a grand jury that sets forth charges against a defendant and states when the alleged crime occurred. An indictment is not a finding of guilt. Guilt can only be determined by a judge or jury after a trial.

**INJUNCTION:** A civil action taken against an individual or firm seeking to stop continued production or distribution of a violative product.

**PROSECUTION:** A criminal action taken against a company or individual charging violation of the law.

**RECALL AND FIELD CORRECTION:** Action taken by a firm to either remove a product from the market or to conduct a field correction. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

**SEIZURE:** An action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the product is located. A U.S. Marshal is then directed by the court to take possession of the goods until the matter is resolved.

**WARNING LETTER:** An informal advisory to a firm communicating the agency's position

on a matter but does not commit FDA to taking enforcement action. The agency's policy is that Warning Letters should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.

For the purpose of the charts and graphs the following descriptive terms are used.

**ADVERSE FINDINGS:** The number of establishment inspections classified "Official Action Indicated" or "Voluntary Action Indicated" and the number of samples analyzed and classified as violative.

**INDUSTRY SURVEILLANCE:** The total number of establishment inspections, sample collections, field examinations and wharf examinations conducted by FDA personnel.

